PHYSICIAN ADMINISTERED DRUGS, VACCINES, AND IMMUNIZATIONS

ELIGIBLE PROVIDERS

In order to receive payment, all eligible servicing and billing provider's National Provider Identifiers (NPI) must be enrolled with South Dakota Medicaid. Servicing providers acting as a locum tenens provider must enroll in South Dakota Medicaid and be listed on the claim form. Please refer to the provider enrollment chart for additional details on enrollment eligibility and supporting documentation requirement.

South Dakota Medicaid has a streamlined enrollment process for eligible ordering, referring, and attending providers that may require no action on the part of the provider as submission of claims constitutes agreement to the South Dakota Medicaid Provider Agreement.

The following providers may bill for physician administered drugs and vaccines/immunizations (hereafter referred to as "vaccines") as permitted by their licensure:

- Clinical nurse specialists
- Health department clinics
- Indian Health Service (IHS)
- Nurse midwives
- Nurse practitioners
- Outpatient and inpatient hospital departments
- Pharmacies
- Physician assistants
- Physicians
- Tribal 638 providers

South Dakota Medicaid does not enroll individual pharmacists.

ELIGIBLE RECIPIENTS

Providers are responsible for checking a recipient's Medicaid ID card and verifying eligibility before providing services. Eligibility can be verified using South Dakota Medicaid's online portal.

The following recipients are eligible for medically necessary services covered in accordance with the limitation described in this chapter:

Coverage Type	Coverage Limitations
Medicaid/CHIP Full Coverage	Medically necessary services covered in accordance with the limitations described in this chapter.

Qualified Medicare Beneficiary – Coverage Limited (73)	Coverage restricted to co-payments and deductibles on Medicare A and B covered services.
Unborn Children Prenatal Care Program (79)	Coverage restricted to pregnancy related services only including medical issues that can harm the life of the mother or baby.

Refer to the Recipient Eligibility manual for additional information regarding eligibility including information regarding limited coverage aid categories.

COVERED SERVICES AND LIMITS

General Coverage Principles

Providers should refer to the General Coverage Principles manual for basic coverage requirements all services must meet. These coverage requirements include:

- The provider must be properly enrolled;
- Services must be medically necessary;
- The recipient must be eligible; and
- If applicable, the service must be prior authorized.

The manual also includes non-discrimination requirements providers must abide by.

Physician Administered Drugs

South Dakota Medicaid covers most drugs and biologics administered in a physician or other licensed practitioner's office that cannot be self-administered. Physician and other licensed practitioners are responsible for ensuring that the treatment is appropriate based on FDA-approved indications, peer-review journals, and standards of practice. To be covered drugs and biologicals must represent an expense to the physician, other licensed practitioner, or legal entity billing Medicaid. Injections by a physician or other licensed practitioner of medications that can be self-administered are not covered unless justified by the recipient's condition.

Administration

For physician administered drugs, in addition to the HCPCS drug code, providers may separately bill the applicable administration procedure CPT code 96372 or 96373. The code may be billed once for each injection administered on a date of service

Units

Providers must ensure that the units of drugs or biologicals administered to patients are accurately reported in terms of the dosage/units specified in the complete HCPCS code descriptor. Prior to submitting claims providers should review the HCPCS code long descriptor. Provider should not bill units based on the way the drug is package, priced, stored or stocked. The following are examples of how to bill units:

- HCPCS drug descriptor is 10 mg. 700mgs of the drug is administered to the recipient. The units billed is 70.

- HCPCS drug descriptor is 5 mcg. 5 mgs of drug is administered to the recipient. The units billed is 1.
- HCPCS drug descriptor is 25 mg. 250 mgs of the drug is administered to the recipient. The units billed is 10.

Pharmacy Acquired Drugs

Drugs that are administered to a patient as part of a clinic or other outpatient visit are not covered under the pharmacy benefit. Do not bill drugs administered during an outpatient visit through the pharmacy POS system. South Dakota Medicaid does not allow "brown-bagging" or "white-bagging" of prescription drugs administered in an office setting. Pharmacies should not dispense drugs directly to a patient if the drugs are intended for use during a clinic or other outpatient visit.

Discarded Portion of Administered Drugs

When a provider must discard the remainder of a single use vial or other single use package after administering a dose or quantity of the drug or biological, provider must bill the amount of the unused and discarded drug on a separate claim line using the JW modifier. Providers are expected to use the package size that minimizes the amount of waste billed to South Dakota Medicaid. For example, if a patient needs 50 mg of drug and the product comes in 50 mg and 100 mg vials, providers should use the 50 mg vial. The line with the JW modifier pays at zero. The recipient may not be billed for discarded drugs.

Donated Drugs

South Dakota Medicaid does not reimburse providers for drugs donated to a recipient. The administration of the drugs by a provider is covered. Do not include the code for the drug on the claim for administration.

340B Drugs

South Dakota Medicaid does not cover drugs acquired through the 340B program. Providers must "carve out" and not bill South Dakota Medicaid for any drugs acquired through this program. For more information refer to the 340B Drugs manual.

National Drug Code (NDC)

Physician administered drugs must be billed with both a HCPCS code and an 11-character NDC with no hyphens or spaces. The Federal Deficit Reduction Act of 2005 (DRA) requires Medicaid state agencies to collect rebates from participating drug manufacturers for physician-administered or dispensed drugs. An NDC is required as it allows the state to identify which manufacture should be billed for rebates. The NDC is found on the drug container such as a vial, bottle, or tube. The NDC submitted on the claim must be the actual NDC number on the package or container from which the medication was administered. Refer to the CMS 1500 Claim Instructions for information regarding reporting the NDC on a claim.

Please refer to the Prior Authorization website for prior authorization forms. Bezlotoxumab (Zinplava)
Bezlotoxumab (Zinplava) does not require prior authorization; the following criteria must be met and documented in the recipients' medical record for coverage of Zinplava:

- The recipient is 18 years of age or older.
- The recipient has a confirmed diagnosis of Clostridium difficile infection (CDI) as evidenced by both of the following:
    - Passage of 3 or more loose bowel movements in 24 or fewer hours; and
    - A positive stool test for toxigenic Clostridium difficile.
- The recipient is starting or is currently receiving appropriate antibiotic treatment for CDI for at least 10 days; and
- Zinplava will be administered during antibacterial drug treatment for recipient's CDI; and
- The recipient is at high-risk for CDI recurrence as evidenced by 2 or more of the following risk factors:
    - Recipient is 65 years of age or older; or
    - Recipient has had one or more previous CDIs requiring treatment in the past 6 months; or
    - Recipient is immunocompromised.

Prior Authorization

The following physician administered drugs require a prior authorization:

- Botulinum Toxin (Botox)
- CAR T Cell Therapy
- Makena
- Spinraza
- Zolgensma
- Synagis
- Tepezza
- Exondys 51
- Luxturna
- Cinryze
- H.P. Acthar
- Soliris
- Ocrevus
- Uplizna
- Ultomiris
- Aduhelm (aducanumab)

Botulinum Toxin (Botox)

Botox requires prior authorization by South Dakota Medicaid and is not covered if treatment is determined to investigational, experimental or cosmetic. Botulinum toxin administration may only be billed every 12 weeks, regardless of the diagnosis. To be medically necessary, the service must meet the following conditions:

- Axillary Hyperhydrosis under the following conditions:
    - For initial therapy, medical records documenting all the following:
        - Potential causes of secondary hyperhidrosis have been ruled out (e.g., hyperthyroidism);

        - The condition is associated with significant functional impairment that is documented in the medical record (e.g., member is unable to perform age-appropriate activities of daily living);
        - The condition is causing persistent or chronic cutaneous conditions (e.g., skin maceration, dermatitis, fungal infections, secondary microbial infections);
        - Condition is refractory to at least 2 months of continuous treatment with a topical agent (e.g., ≥20% aluminum chloride) unless use results in severe dermatitis; and
        - Condition is refractory to at least 2 months of continuous treatment with conventional systemic pharmacotherapy (e.g., anticholinergics, beta blockers, or benzodiazepines) unless clinically contraindicated.
    - For continuation of therapy, medical records documenting both of the following:
        - Documentation of positive clinical response to botulinum toxin therapy; and
        - Statement of expected frequency and duration of proposed botulinum toxin treatment.
- Chronic migraine headaches under the following conditions:
    - Recipient has been evaluated by a neurologist or headache specialist; and
    - For prevention of chronic migraine headaches:(more than 14 days per month with headaches lasting 4 hours a day or longer), in adults who have tried, (if not medically contraindicated), and failed trials of at least three medications selected from at least two classes of migraine headache prophylaxis medications listed below of at least 2 months (60 days) duration for each medication:
        - Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (e.g., losartan, valsartan, lisinopril);
        - Anti-depressants (e.g., amitriptyline, clomipramine, doxepin, mirtazapine, nortryptiline, protriptyline);
        - Anti-epileptic drugs (e.g., divalproex, gabapentin, topiramate, valproic acid);
        - Beta blockers (e.g., atenolol, metoprolol, nadolol, propranolol, timolol);
        - Calcium channel blockers (e.g., diltiazem, nifedipine, nimodipine, verapamil).
- Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary when documentation is submitted showing that:
    - Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial of 24 weeks; or
    - Migraine headache duration was reduced by at least 100 total hours per month (when compared to the pre-treatment average) by the end of the initial trial.
- All other uses for Botox must be medically necessary and meet medical necessity criteria:
    - It is consistent with the recipient's symptoms, diagnosis, condition, or injury;
    - It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group;
    - It is provided in response to a life-threatening condition; to treat pain, injury, illness, or infection; to treat a condition that could result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition;

- It is not furnished primarily for the convenience of the recipient or the provider; and There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly.

Hydroxyprogesterone Caproate (Makena)

Makena requires prior authorization by South Dakota Medicaid. Makena is FDA approved to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Makena is not intended for use in women with multiple gestations or other risk factors for preterm birth. If prior authorized, approval will be granted for treatment beginning between weeks 16 and 20 of gestation and continuing until week 37 of gestation or delivery, whichever occurs first.

Spinraza (Nusinersen)

Spinraza is covered for the treatment of Spinal Muscular Atrophy (SMA) when prior authorized for patients who meet all the following criteria:

Initial Therapy:

- Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:
  - The mutation or deletion of genes in chromosome 5q resulting in one of the following:
    - Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)1,5; or
    - Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]); and
  - Patient has 3 copies or less of SMN2: and
- Patient is not dependent on either of the following:
  - Invasive ventilation or tracheostomy
  - Use of non-invasive ventilation beyond use for naps and nighttime sleep; and

  Submission of medical records (e.g., chart notes, laboratory values) including the baseline Hammersmith Functional Motor Scale Expanded (HFMSE) exam by a board certified neurologist. If the HFMSE is not appropriate for the patient, provide the test used to establish baseline motor ability; and
- Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; and
- One of the following:
  - Patient has not previously received gene replacement therapy for the treatment of SMA; or
  - One of the following:
    - Both of the following:
      - Patient recently received gene replacement therapy within the previous 6 months; and

        - Patient has experienced a declination in clinical status since receipt of gene replacement therapy; or
    - Both of the following:
        - Patient has previously received gene replacement therapy; and
        - Patient has experienced a declination in clinical status that represents a potential abatement of gene therapy efficacy; and
- Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; and
- Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose; and
- Initial authorization will be for no more than 4 loading doses.

Continuation Therapy:

- Diagnosis of spinal muscular atrophy type I, II, or III by, or in consultation with, a neurologist with expertise in the diagnosis of SMA; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:
    - The mutation or deletion of genes in chromosome 5q resulting in one of the following:
        - Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)1,2; or
        - Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2]); and
    - Patient has 3 copies or less of SMN2: and
- Patient is not dependent on either of the following:
    - Invasive ventilation or tracheostomy
    - Use of non-invasive ventilation beyond use for naps and nighttime sleep; and
- One of the following:
    - Patient has not previously received gene replacement therapy for the treatment of SMA; or
    - Both of the following:
        - Patient has previously received gene replacement therapy; and
        - Patient has experienced a declination in clinical status that represented a potential failure or abatement of gene therapy efficacy; and
- Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by the initial test used to establish baseline motor ability unless that test is no longer appropriate for the patient; and
    - One of the following:
        - Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline; or
        - Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so; or
    - Both of the following:

        - Patient was prescribed Spinraza due to clinical declination after receipt of gene therapy; and
        - Patients clinical status has stabilized after receipt of Spinraza therapy; and
- Spinraza is prescribed by, or in consultation with, a neurologist with expertise in the treatment of SMA; and
- Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures; and
- Spinraza dosing for SMA is within accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose; and
- Reauthorization will be for no more than 3 maintenance doses (12 months).

Spinraza is not covered for:

- Spinal muscular atrophy without chromosome 5q mutations or deletions.
- Routine concomitant treatment of SMA in patients who have previously received gene replacement therapy.
- Type 0 or IV SMA.

<u>Zolgensma</u>

- Zolgensma is covered with a prior authorization for patients who meet all the following criteria:

- Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation or deletion of genes in chromosome 5q resulting in one of the following:
    - Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); or
    - Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]); and
- One of the following:
    - Diagnosis of SMA by a board-certified pediatric neurologist with expertise in the diagnosis of SMA; or
    - Both of the following:
- Diagnosis of SMA based on the results of SMA newborn screening; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming that patient has 3 copies or less of SMN2 gene: and
- For use in a neonatal patient born prematurely, the full-term gestational age has been reached; and
- One of the following:
    - Both of the following:
        - Patient is less than or equal to 6 months of age
        - Patient does not have advanced SMA at baseline (e.g., complete paralysis of limbs); or
    - All the following:
        - Patient is greater than 6 months of age, but less than 2 years of age; and

        - One of the following:
            - Both of the following:

- Patient has previously received SMN modifying therapy [e.g. Spinraza (nusinersen)] for the treatment of SMA before 6 months of age with positive clinical response; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming patient does not have advanced SMA as defined by the fact that the patient has not shown evidence of clinical decline while receiving SMN modifying therapy [e.g. Spinraza (nusinersen]; or
    - Both of the following:
- Patient has previously received SMN modifying therapy [e.g. Spinraza (nusinersen)] for the treatment of later-onset SMA before 2 years of age with positive clinical response; and
- Submission of medical records (e.g., chart notes, laboratory values) confirming patient does not have advanced SMA as defined by the fact that the patient has not shown evidence of clinical decline while receiving SMN modifying therapy [e.g. Spinraza (nusinersen)]; or
    - Patient has recently been diagnosed with symptomatic later-onset SMA within the previous 6 months; and
- Patient is not dependent on either of the following:
    - Invasive ventilation or tracheostomy
    - Use of non-invasive ventilation beyond use for naps and nighttime sleep; and
- Zolgensma is prescribed by a board-certified pediatric neurologist with expertise in the treatment of SMA; and
- Patient is not to receive routine concomitant SMN modifying therapy [e.g., Spinraza (nusinersen)] (patient's medical record will be reviewed and any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval; patient access to subsequent SMN modifying therapy will be assessed according to respective coverage policy of concomitant agent); and
- Patient does not have an elevated anti-AAV9 antibody titer above 1:50; and
- Patient has LFTs less than 2X ULN determined by a certified lab; and
- Patient has received no treatment with immunosuppressive therapy in the 3 months prior to starting Zolgensma treatment (e.g., corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, intravenous immunoglobulin, rituximab); and
- Patient does not have symptoms of active viral infection; and
- Physician attests that the patient, while under the care of the physician, will be assessed on the Hammersmith Functional Motor Scale Expanded (HFMSE) assessment (or the initial test used to establish baseline motor ability unless that test is no longer appropriate for the patient) during subsequent office visits while the patient is 2 to 3 years of age or older following exam scales during subsequent office visits; and
- Physician acknowledges that South Dakota Medicaid may request documentation, not more frequently than biannually, and not for a period to exceed 3 years, of follow-up patient assessment(s) including, but not necessarily limited to, HFMSE assessments or other applicable assessments while the patient is under the care of the physician; and
- Patient will receive prophylactic prednisolone (or glucocorticoid equivalent) prior to and following receipt of Zolgensma in accordance with the United States Food and Drug Administration (FDA) approved Zolgensma labeling; and

- Patient will receive Zolgensma intravenously in accordance with the FDA approved labeling, 1.1 x 1014 vector genomes (vg) per kg of body weight; and
- Patient has never received Zolgensma treatment in their lifetime; and
- Authorization will be for no longer than 14 days from approval or until 2 years of age, whichever is first.

Zolgensma is not covered for:

- The treatment of pre-symptomatic patients diagnosed by newborn screening who have more than 3 copies of the SMN2 gene.
- The treatment of symptomatic later-onset SMA older than 2 years of age.
- SMA without chromosome 5q mutations or deletions.
- The routine combination treatment of SMA with concomitant SMN modifying therapy.

Synagis/Respigam

Synagis and Respigam are covered by South Dakota Medicaid if prior authorized. It is only covered from November 1st of each calendar year through March 31st of the following calendar year. It may be covered outside of this time period if determined medically necessary by the South Dakota Medicaid Medical Director. A child must meet all of the following criteria:

- The medication has been recommended by a neonatologist, pediatric pulmonologist, or pediatric cardiologist; and
- The child meets one of the following categories listed below:
    - Children under 1 year of age at the onset of RSV season who were 28 & 0/7 weeks or less gestational age at birth; or
    - Children under 6 months of age at the onset of the RSV season who were born between 28 & 1/7 and 32 & 0/7-weeks gestational age at birth; or
    - Children under 3 months of age at the onset of the RSV season or who are born during the RSV season (11/1-3/31) who were between 32 & 1/7 and 35 & 0/7 weeks gestational age at birth with one of these 2 risk factors: day care attendance or a sibling in the household less than 5 years of age; or
    - Children under 2 years of age at the onset of the RSV season with evidence of ongoing lung disease such as bronchopulmonary dysplasia or cystic fibrosis requiring treatment with oral bronchodilators, supplemental oxygen, diuretics, or nebulized or inhaled medications to stabilize the disease in the last 6 months; or
    - Children under 2 years of age at the onset of the RSV season with evidence of hemodynamically significant cyanotic or acyanotic congenital heart disease and 1 of the following: receiving medication to control congestive heart failure, moderate to severe pulmonary hypertension, or undergoing surgical procedures that use cardiopulmonary bypass; or
    - Children under 2 years of age at the onset of the RSV season with immunodeficiencies that may make them more susceptible to severe lower respiratory tract disease related to RSV; or
    - Any child under 2 years of age at the onset of the RSV season felt to be at high risk for significant lower respiratory tract illness related to RSV.

Providers must submit the request using the Synagis Prior Authorization Request Form.

Tepezza

Tepezza (CPT J3241) is covered when the following criteria is met, and it is prior authorized by South Dakota Medicaid:

- Recipient must be 18 years of age or older; and
- Tepezza is prescribed by, or in consultation with, an endocrinologist or ophthalmologist with expertise in the treatment of Graves' disease associated with thyroid eye disease (TED); and
- The recipient has had an inadequate response with, or has a contraindication or intolerance to, corticosteroids used for the treatment of TED (e.g., prednisone, methylprednisolone, dexamethasone); and
- Recipient has a diagnosis of moderate to severe Thyroid associated orbitopathy (thyroid eye disease):
  - Associated with at least one of the following:
    - Lid retraction ≥ 2 mm; or
    - Moderate or severe soft tissue involvement; or
    - Exophthalmos ≥ 3 mm above normal for race and gender; or
    - Diplopia; and
  - One of the following:
    - Patient must be euthyroid with thyroid function under control; or
    - Mild hypothyroidism or hyperthyroidism undergoing treatment to correct and/or maintain euthyroid; and
- Onset of TED symptoms within 9-12 months prior to starting Tepezza treatment; and
- TED clinical activity score of greater than or equal to four (4); and

Clinical Activity Score for Graves Orbitopathy		
For each item present, one (1) point is given. The sum of these points is the clinical activity score		
Pain	1	Painful oppressive feeling on or behind the globe, during the last four (4) weeks
	2	Pain on attempted u, side or down gaze, during the last four (4) weeks
Redness	3	Redness of eyelid(s)
	4	Diffuse redness of the conjunctiva, covering at least one (1) quadrant
Swelling	5	Swelling of eyelid (s)
	6	Chemosis
	7	Swollen caruncle
	8	Increase of proptosis of greater than or equal to 2mm during a period of 1-3 months
Impaired function	9	Decrease of eye movements in any direction greater than or equal to 5o during a period of 1-3 months
	10	Decrease of visual activity of greater than or equal to one (1) line(s) on the Snellen chart (using a pinhole) during a period of 1-3 months

- Recipient does not require immediate surgical ophthalmological intervention; and
- Recipient does not have clinically significant optic neuropathy (Individual has not had a decrease in best corrected visual acuity (BVCA) within the previous six months, i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement; and
- Recipient does not have corneal decompensation unresponsive to medical management; and
- Recipient is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases; and
- If the recipient is a diabetic, the recipient is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes; and
- Individual is not pregnant.

Exondys 51

Exondys 51 (eteplirsen) is covered when the following criteria is met, and it is prior authorized by South Dakota Medicaid:

- Prescribed by or in consultation with provider in neurology with expertise in neuromuscular disorders.
- Documentation of confirmed mutation that DMD gene is amenable to exon 51 skipping (submission of medical records, genetic testing, etc.) ***
- Documentation of baseline 6-minute walk or NorthStar Ambulatory Assessment no longer than one month prior to beginning Exondys 51.
- If non-ambulatory, baseline functional level assessment is required, no longer than one month prior to beginning Exondys 51, by:
    - Brooke upper extremity scale (less than or equal to 5); and
    - Forced vital capacity assessment (of 30% or more); and
    - Stable cardiac function with left ventricular ejection fraction (LVEF) > 40%.
- Not ventilator dependent
- Not being used in conjunction with other exon skipping therapies for DMD (ie Vyondys 53, Amondys 45, Viltepso).
- Initiated before the age of 14.
- Must be on a stable dose of corticosteroids for 6 months unless contraindicated or adverse effects were previously experienced.

Criteria for continuation of therapy:

- Continued follow-up with neurology provider and/or neuromuscular clinic.
- Documentation of response to therapy every 6 months as evidenced by all of the following:
    - Documentation of repeat 6-minute walk or NorthStar Ambulatory Assessment that shows stability or improvement in ambulatory function.
    - Stability or improvement in respiratory function.
- Must continue to meet initial criteria.

Luxturna (voretigene neparvovec-rzyl)

Luxturna is covered for the treatment of inherited retinal disease (IRD) when prior authorized for patients who meet all the following criteria:

Initial Therapy:

- Prescribed by an ophthalmologist or retinal specialist/surgeon; and
- 3 years of age or older; and
- Confirmed diagnosis of biallelic RPE65 mutation-associated retinal dystrophy such as Leber's congenital amaurosis (LCA), retinitis pigmentosa (RP) or early onset severe retinal dystrophy (EOSRD); and
- Has not previously received RPE65 gene therapy in intended eye; and
- Confirmation of sufficient viable retinal cells in each eye planned for treatment by treating physician within the past 6 months. Verification must be documented and evident by one or more of the following:
    - Optical coherence tomography (OCT) thickness >100um with presence of neural retina in the posterior pole; or
    - > 3 disc areas of retina free of atrophy and/or pigmentary degeneration in the posterior pole; or
    - Intact visual field within 30° of fixation as measured by a III4e isopter or equivalent; and
- Injection in second eye is at least 6 days after the first eye; and
- No history of intraocular surgery within the prior 6 months

Continuation of Therapy:

- Treatment is limited to a single dose per eligible eye, per lifetime
- Authorization can be given for both eyes if dates and plan are specified for each surgery OR authorization must be obtained for each eye separately

<u>Cinryze (C1 esterase inhibitor [human])</u>
Cinryze is covered for the treatment of hereditary angioedema (HAE) when prior authorized for patients who meet all the following criteria:

Initial Therapy:

- Prescribed by or in consultation with an immunologist, hematologist, or allergist; and
- 6 years of age or older; and
- Diagnosis of hereditary angioedema (HAE) with supportive documentation:
    - Hereditary Angioedema Type I
        - Low C4 level; and
        - Low C1-INH antigenic level; or
    - Hereditary Angioedema Type II
        - Low C4 level; and
        - Normal or elevated C1-INH antigenic level and low C1-INH functional level; or
    - Hereditary Angioedema Type III
        - No evidence of urticaria; and
        - Normal C4 level; and

    - Normal C1-INH antigenic level and normal C1-INH functional level; and
    - Documentation of a family history of angioedema, and failure to respond to chronic, high-dose antihistamine therapy, or a known hereditary angioedema causing mutation; and
- Prescribed for HAE prophylaxis; and
- Not used in combination with other products for prophylaxis of HAE; and
- Documentation of failure, contraindication, or intolerance to ALL of the following:
    - Attenuated androgens (danazol, stanozolol) and antifibrinolytics (aminocaproic acid, tranexamic acid); and
- Documentation of at least one of the following:
    - 2 or more severe HAE attacks (debilitating GI or cutaneous effects); or
    - Disabling symptoms more than 5 days per month; or
    - History of airway compromise or recurrent laryngeal attacks; and
- Documentation of lack of control or access to acute medications; and
- Medications that may exacerbate HAE have been evaluated and discontinued when appropriate (i.e., ACE inhibitors, estrogen-containing medications, angiotensin II receptor blockers)

Continuation of Therapy:

- Initial criteria has been met or current successful use of Cinryze; and
- Reauthorization at 6 months and then every 12 months thereafter; and
- Documentation of positive clinical response as indicated by both of the following:
    - Clinically significant reduction in the rate and/or number of HAE attacks; and
    - Reduction in the use of on-demand therapies for acute attacks

<u>H.P. Acthar (corticotropin- generic or name brand)</u>

H.P. Acthar is indicated for:

- Infantile spasms in infants and children under 2 years of age; or
- Exacerbations of multiple sclerosis in adults

H.P. Acthar is covered for the treatment of the above listed medical conditions when prior authorized for patients who meet the following criteria:

Initial Therapy:

- For Infantile Spasms:
    - Requested by or in consultation with a pediatric neurologist; and
    - Diagnosis or infantile spasms (West Syndrome); and
    - Less than 2 years of age
- For Multiple Sclerosis Exacerbations:
    - Requested by or in consultation with a neurologist; and
    - 18 years of age or older; and
    - Diagnosis of multiple sclerosis (MS); and
    - Documentation of acute MS exacerbation; and

- Previous failure, contraindication, or intolerance to oral and injectable glucocorticoids; and
- Documentation of current use of disease modifying therapy for MS

Continuation of therapy:

- For Infantile Spasms
  - Approved for 4 weeks only, 2 weeks of regular use followed by approximately 2 weeks of tapering
  - Reauthorization can be considered for an additional 4 weeks if there is a relapse in spasm symptoms after H.P. Acthar is discontinued
- Multiple Sclerosis Exacerbations
  - Approved for 3 weeks only

<u>Soliris (eculizumab)</u>

Soliris is indicated for:

- Adults with anti-ACHR+ generalized myasthenia gravis (gMG)
- Adults with anti-AQP4 antibody positive Neuromyelitis Optica Spectrum Disorder (NMOSD)
- Adult or pediatric patients 2 months or older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy
- Adults with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis

Soliris is covered for the treatment of the above listed medical conditions when prior authorized for patients who meet all the following criteria:

Initial Therapy:

- For all indications:
  - Documentation of meningococcal vaccination following current Advisory Committee on Immunization Practices (ACIP) guidelines
- For gMG:
  - Requested by or in consultation with a neurologist; and
  - Individual is 18 years of age or older; and
  - Labs confirming presence of anti-ACHR antibodies; and
  - Documentation of inadequate response or contraindication to pyridostigmine and corticosteroids; and
  - One of the following:
    - Failed treatment with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus etc.) over the course of the last 12 months; or
    - Has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and

  - Supportive documentation of clinical rationale to initiate Soliris for this patient, such as clinical presentation, disease-related complications, recent medical history, visits related to gMG and any contraindications to any agents used in treatment of gMG; and
  - Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and
  - Baseline Quantitative Myasthenia Gravis (QMG) score; and
  - MG-Activities of Daily Living (MG-ADL) total score of ≥6
- For NMOSD:
  - Requested by or in consultation with a neurologist; and
  - Individual is 18 years or older; and
  - Seropositive aquaporin-4 (AQP4) antibodies; and
  - Documented diagnosis of NMOSD with at least one core clinical characteristic below:
    - Optic neuritis; or
    - Acute myelitis; or
    - Area postrema syndrome or episode of otherwise unexplained hiccups or nausea and vomiting; or
    - Acute brainstem syndrome; or
    - Symptomatic narcolepsy; or
    - Acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; or
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; and
  - History of failure, contraindication, or intolerance to rituximab, inebilizumab (Uplizna), and satralizumab-mwge (Enspryng); and
  - Baseline Expanded Disability Status Scale score (EDSS); and
  - History of at least 2 relapses in last 12 months or 3 relapses in the last 24 months with at least 1 relapse in the last 12 months
- For aHUS:
  - Requested by or in consultation with a hematologist or nephrologist; and
  - Individual is 2 month of age or older; and
  - Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) and thrombotic thrombocytopenic purpura (TTP) (ADAMTS-13) have been ruled out as well as other causes and coexisting diseases or conditions; and
  - Documented baseline values for
    - Serum lactate dehydrogenase (LDH); and
    - Serum creatinine/eGFR; and
    - Platelet count; and
    - Frequency of plasma exchange/infusion requirement
- For PNH:
  - Requested by or in consultations with a hematologist, oncologist, or immunologist; and
  - Individual is 18 years or older; and
  - PNH confirmed by flow cytometry (must include at least 2 different reagents tested on at least 2 cell lineages) demonstrating that individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) linked proteins (CD55, CD59 etc.); and
  - Documentation of one or more of the following indicating systemic complications:

        - Fatigue, abdominal pain, dysphagia/odynophagia, shortness of breath, chest pain/pressure, anemia, hemoglobinuria, end organ damage, thrombosis, etc.; and
    - History of packed red blood cell transfusion(s) due to PNH with associated documentation showing the frequency of transfusions; and
    - Documented high lactate dehydrogenase (LDH) activity (defined as ≥1.5 x upper limits of normal (ULN)) with baseline hemoglobin level

Continuation of Therapy:

- For all indications:
    - Initial approval for 6 months and then every 12 months thereafter; and
    - Initial approval criteria has been met; and
    - Absence of adverse reactions/complications from the drug such as serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, thrombotic microangiopathy complications (TMA), etc.; and
- For gMG renewal:
    - Improvement (reduction in score) in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score from pretreatment baseline; or
    - Improvement in the Quantitative Myasthenia Gravis (QMG) total score
- For NMO renewal:
    - Positive clinical response including maintained or improved EDSS score, decreased relapse rate
- For aHUS renewal:
    - Positive clinical response as indicated by one or more of the following:
        - Decrease in serum LDH from pretreatment baseline; or
        - Stabilization/improvement in renal function (serum creatinine/eGFR) from pretreatment baseline; or
        - Increase in platelet count from pretreatment baseline; or
        - Decrease in plasma exchange/infusion requirement from pretreatment baseline
- For PNH renewal:
    - Positive clinical response as indicated by one or more of the following:
        - Stabilization or decrease in serum LDH from pretreatment baseline; or
        - Stabilization/improvement in hemoglobin level from pretreatment baseline; or
        - Decrease in packed RBC transfusion requirement from pretreatment baseline

<u>Ocrevus (ocrelizumab)</u>
Ocrevus is indicated for:

- Adults with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
- Adults with primary progressive MS

Ocrevus is covered for the treatment of the above listed medical conditions when prior authorized for patients who meet all the following criteria:

Initial Therapy for Relapsing Multiple Sclerosis:

- Prescribed by or in consultation with a neurologist; and
- 18 years of age or older; and
- Documentation of hepatitis B virus and quantitative serum immunoglobulin screening and no active hepatitis B infection; and
- Not being used in combination with other MS disease modifying therapies; and
- One of the following:
    - Previous trial in the past 12 months of at least two MS disease modifying drug therapies that were not tolerated or ineffective as evidenced by disease progression; or
    - Explanation of contraindications for other MS disease modifying drug therapies; and
- Documented need to use as first line therapy due to severity of MS or if they are at higher risk of poor long-term outcome (those with spinal cord involvement, highly active disease, poor relapse recovery, etc.)

Initial Therapy for Primary Progressive Multiple Sclerosis:

- Prescribed by or in consultation with a neurologist; and
- 18 years of age or older; and
- Documentation of hepatitis B virus and quantitative serum immunoglobulin screening and no active hepatitis B infection; and
- Not being used in combination with other MS disease modifying drug therapies

Continuation of therapy:

- Initial criteria has been met; and
- No documented severe and/or potentially life-threatening adverse event that occurred during or following the previous infusion; and
- Documentation of disease improvement or stabilization
- Reauthorization required every 12 months

<u>Uplizna (inebilizumab-cdon)</u>
Uplizna is covered for the treatment of adults with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive when prior authorized for patients who meet all the following criteria:

Initial Therapy:

- Prescribed by or in consultation with a neurologist; and
- 18 years of age or older; and
- Seropositive aquaporin-4 (AQP4) antibodies; and
- Documented diagnosis of NMOSD with at least one core clinical characteristic as below:
    - Optic neuritis; or
    - Acute myelitis; or
    - Area postrema syndrome or episode of otherwise unexplained hiccups or nausea and vomiting; or
    - Acute brainstem syndrome; or
    - Symptomatic narcolepsy; or

  - Acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions; or
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; and
- Documentation of screening for hepatitis B, quantitative serum immunoglobulins, and tuberculosis prior to starting; and
- Documented previous failure, intolerance, or contraindication to at least two of the following:
  - Rituximab therapy, azathioprine mycophenolate, methotrexate, tocilizumab; and
- Documentation of at least one relapse in the last 12 months or two relapses in the last 2 years; and
- Not being used in combination with other biologics for NMOSD (eculizumab, rituximab, satralizumab, tocilizumab, etc.)

Contraindications:
- Active Hepatitis B infection; and
- Active or untreated latent tuberculosis

Continuation of therapy:
- Initial criteria has been met; and
- Reauthorization required every 12 months; and
- Documentation of positive clinical response with reduction in the number and/or severity of relapses or signs and symptoms of NMOSD

<u>Ultomiris (ravulizumab-cwvz)</u>
Ultomiris is indicated for:
- Adults with anti-ACHR+ generalized myasthenia gravis (gMG)
- Adult and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
- Adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH)

Ultomiris is covered for the treatment of the above listed medical conditions when prior authorized for patients who meet all the following criteria:

Initial Therapy:
- For all indications:
  - Documentation of meningococcal vaccination following current Advisory Committee on Immunization Practices (ACIP) guidelines
- For gMG:
  - Requested by or in consultation with a neurologist; and
  - 18 years of age or older; and
  - Labs confirming presence of anti-ACHR antibodies; and
  - Documentation of inadequate response or contraindication to pyridostigmine and corticosteroids; and
  - One of the following:

        - Failed treatment with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus etc.) over the course of the last 12 months; or
        - Has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
    - Supportive documentation of clinical rationale to initiate Ultomiris for this patient, such as clinical presentation, disease-related complications, recent medical history, visits related to gMG and any contraindications to any agents used in treatment of gMG; and
    - Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; and
    - Baseline Quantitative Myasthenia Gravis (QMG) score; and
    - MG-Activities of Daily Living (MG-ADL) total score of ≥6
- For aHUS
    - Requested by or in consultation with a hematologist or nephrologist; and
    - Individual is 1 month of age or older; and
    - Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) and thrombotic thrombocytopenic purpura (TTP) (ADAMTS-13) have been ruled out as well as other causes and coexisting diseases or conditions; and
    - Documented baseline values for
        - Serum lactate dehydrogenase (LDH); and
        - Serum creatinine/eGFR; and
        - Platelet count; and
        - Frequency of plasma exchange/infusion requirement
- For PNH:
    - Requested by or in consultations with a hematologist, oncologist, or immunologist; and
    - Individual is 1 month of age or older; and
    - PNH confirmed by flow cytometry (must include at least 2 different reagents tested on at least 2 cell lineages) demonstrating that individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) linked proteins (CD55, CD59 etc.); and
    - Documentation of one or more of the following indicating systemic complications:
        - Fatigue, abdominal pain, dysphagia/odynophagia, shortness of breath, chest pain/pressure, anemia, hemoglobinuria, end organ damage, thrombosis, etc.; and
    - History of packed red blood cell transfusion(s) due to PNH with associated documentation showing the frequency of transfusions; and
    - Documented high lactate dehydrogenase (LDH) activity (defined as ≥1.5 x upper limits of normal (ULN) with baseline hemoglobin level

Continuation of Therapy:

- For all indications:
    - Initial approval for 6 months and then every 12 months thereafter; and

- Initial approval criteria has been met; and
- Absence of adverse reactions/complications from the drug such as serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections, thrombotic microangiopathy complications (TMA), etc.; and

- For gMG renewal:
  - Improvement (reduction in score) in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score from pretreatment baseline; or
  - Improvement in the Quantitative Myasthenia Gravis (QMG) total score
- For aHUS renewal:
  - Positive clinical response as indicated by one or more of the following:
    - Decrease in serum LDH from pretreatment baseline; or
    - Stabilization/improvement in renal function (serum creatinine/eGFR) from pretreatment baseline; or
    - Increase in platelet count from pretreatment baseline; or
    - Decrease in plasma exchange/infusion requirement from pretreatment baseline
- For PNH renewal:
  - Positive clinical response as indicated by one or more of the following:
    - Stabilization or decrease in serum LDH from pretreatment baseline; or
    - Stabilization/improvement in hemoglobin level from pretreatment baseline; or
    - Decrease in packed RBC transfusion requirement from pretreatment baseline

Aduhelm (aducanumab)

Indication:

- Aduhelm is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease and should be initiated during the mild cognitive impairment or mild dementia stage of the disease.

Criteria for Prior Authorization Approval:

- Must be prescribed by a neurology provider
- Must be 50 years of age or older
- Confirm the presence of amyloid beta pathology with the use of a PET scan prior to initiating treatment
- Must have mild cognitive impairment (MCI) or mild dementia as evidenced by all the following:
  - Mini-mental State Examination (MMSE) score of 24-30
  - Clinical Dementia Rating global score (CDR-GS) of 0.5
- Documentation provided that all other medical and neurological conditions that might contribute to the cognitive impairment have been ruled out
- Obtain a recent (within one year) brain MRI prior to initiating treatment.
- Documented plan to obtain repeat brain MRIs prior to the 5th, 7th, 9th, and 12th infusion for monitoring of the development of amyloid related imaging abnormalities (ARIA)
- Documentation showing trial with failure after at least 4 months of continuous therapy , intolerance, or contraindication to EITHER of the following:
  - Cholinesterase inhibitor (e.g. donepezil)
  - Memantine

- None of the following are present:
  - Stroke, TIA, or unexplained loss of consciousness in the last year
  - Clinically significant unstable psychiatric illness in the past 6 months
  - History of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within the past year
  - Impaired renal or liver function
  - Significant systemic illness or infection in the past 30 days
  - Bleeding disorder, cerebrovascular abnormalities, or relevant brain hemorrhage
  - Contraindication to MRI or PET scans
  - Documentation of alcohol or substance abuse in the past year
  - Use of antiplatelet or anticoagulant, with the exception of aspirin at a prophylactic dose or less

Criteria for Continuation of therapy:

- Must continue to meet initial criteria
- Documented plan to obtain follow-up MRIs at the recommended intervals for monitoring of amyloid related imaging abnormalities (ARIA-E and ARIA-H) and appropriate plan if discovered
- Repeat cognitive testing shows all the following:
  - CDR-GS of 0.5-1.0
  - MMSE score greater than or equal to 18

Vaccine Coverage

South Dakota Medicaid covers medically necessary vaccines and follows the Center for Disease Control immunization schedule, which is available on the CDC website: https://www.cdc.gov/vaccines/schedules/index.html.
Vaccines may be administered by physicians, other licensed practitioners, or nurses as allowed within their scope of licensure.

Pharmacy Vaccines

Refer to the Pharmacy Services manual for coverage, reimbursement, and claim instructions.

Vaccine for Children Program

Providers must obtain vaccines for recipients 18 years of age and under from the Vaccines for Children Program if the vaccine is available through the program. A list of available vaccines is provided here. South Dakota Medicaid reimburses the administration fee for vaccines available through this program; vaccines are paid at $0. Providers must bill state supplied vaccines with the SL modifier, indicating the vaccine was supplied through the Vaccine for Children's program. Claims for vaccines that are available through the Vaccines for Children program for recipients 18 years of age and under that do not include the SL modifier will pay at $0.

If state supplied vaccines is temporarily unavailable from the VFC program, you must submit the claim on paper with supporting documentation such as a letter from the Department of Health stating they are out of the vaccine.

Pediatric Vaccination Counseling

South Dakota Medicaid covers vaccination counseling by providers authorized to administer COVID-19 and childhood vaccines, including those authorized under the HHS COVID-19 PREP Act declaration, for children under age 21. Pediatric vaccination counseling consists of discussing CDC vaccine recommendations, benefits, possible side effects, and answering any questions the recipient or their parents have regarding the vaccine(s). Providing a handout or written information does not constitute counseling. Counseling may be provided to a parent or guardian if age appropriate and for the direct benefit of the child. Vaccine counseling and the types of vaccine counseled on must be documented in the medical record. Vaccine counseling is considered included in a well-child visit and is not separately billable in addition to a well-child visit. Counseling is not separately reimbursed if it is or can be included in a vaccine administration code. Pediatric vaccination counseling can be billed using the following codes:

- **G0312 or G0313** - Pediatric vaccine counseling. One unit of G0312 or G0313 is inclusive of all counseling provided that day, including if counseling was for multiple types of non-COVID-19 vaccines.
- **G0314 or G0315** - COVID-19 pediatric vaccine counseling. May be billed in addition to G0312 or G0313. Coverage is temporary and in effect through one year after the end of the COVID-19 public health emergency.

A total of six counseling sessions (three for each code) per recipient, per calendar, year are reimbursable. Counseling may be provided via telemedicine. Counseling may also be provided via audio only if the visit was initiated by the recipient and the recipient does not have access to face-to-face audio/visual telemedicine technology. Telemedicine and audio only services must be billed in accordance with the Telemedicine Services billing manual.

FQHC/RHCs

Refer to the FQHC/RHCs manual for coverage, reimbursement, and claim instructions.

IHS/Tribal 638 Facilities

Refer to the IHS and Tribal 638 Facilities manual for coverage, reimbursement, and claim instructions.

Postpartum Coverage

Vaccinations during postpartum coverage are covered if indicated by the CDC. Please note that postpartum coverage may end before the full series of Hepatitis A and Hepatitis B vaccines are administered and the recipient may not have continued Medicaid coverage.

NON-COVERED SERVICES

General Non-Covered Services

Providers should refer to ARSD 67:16:01:08 or the General Coverage Principles manual for a general list of services that are not covered by South Dakota Medicaid.

Vaccine Non-Covered Services

A vaccine code is not covered when billed without a vaccine administration code. A vaccine administration code is not covered when billed without a vaccine code. Reimbursement for vaccines is

not available as a service provided by school districts under the individualized education program (IEP) or care plan.

Documentation Requirements

General Requirements
Providers must keep legible medical and financial records that fully justify and disclose the extent of services provided and billed to South Dakota Medicaid. These records must be retained for at least 6 years after the last date a claim was paid or denied. Please refer to the Documentation and Record Keeping manual for additional requirements.

Reimbursement and Claim Instructions

Timely Filing
South Dakota Medicaid must receive a provider's completed claim form within 6 months following the month the service was provided. Requests for reconsiderations will only be considered if they are received within the timely filing period or within 3 months of the date a claim was denied. The time limit may be waived or extended by South Dakota Medicaid in certain circumstances. Providers should refer to the General Claim Guidance manual for additional information.

Third-Party Liability
Medicaid recipients may have one or more additional source of coverage for health services. South Dakota Medicaid is generally the payer of last resort. Providers must pursue the availability of third-party payment sources and should use the Medicare Crossover or Third-Party Liability billing instructions when applicable. Providers should refer to the General Claim Guidance manual for additional information.

Reimbursement
The rate of payment for physician administered drugs, vaccines, and administration codes is limited to the lesser of the provider's usual and customary charge or the amount specified on the department's physician non-laboratory services fee schedule. If the procedure code is not listed in the fee schedule, the procedure is payable at 40 percent of the provider's usual and customary charge. Claims for vaccines that are available through the Vaccines for Children program pay at $0.

Physician administered drugs and vaccines provided by a nurse practitioner, clinical nurse specialist, or physician assistant are reimbursed at the same rate as a physician.

Claim Instructions
Physician administered drugs, vaccines, and administration are billed on a CMS 1500 Claim Form with the exception of IHS, Outpatient Hospitals, and Inpatient Hospitals which must be billed on a UB-04 claim form. Please refer to our website for CMS 1500 and UB-04 claim instructions.

The vaccine code should be billed as 1 unit per vaccine; do not bill in milliliters. Flu vaccine claims do not require a physician or other licensed practitioner order. All other vaccines must include the ordering physician or other licensed practitioner's name and NPI number in block 17 and 17b of the claim form.

UB-04 Claims Documentation
An itemized invoice must be submitted with claims that include billed charges totaling a $100,000 or more for Revenue Codes 250-259, 630-636, and 890-899.

Hospitals are required to report vaccine administration charges under the revenue code 0771.

Vaccines for Children Claim Instructions
Providers must bill state supplied vaccines with the SL modifier.

REFERENCES

- Administrative Rule of South Dakota (ARSD)
  - 67:16:11:05.01. Rate of payment – Immunizations
  - 67:16:02:03. Rate of payment – (9)
  - 67:16:02:16. Billing requirements -- Modifier codes -- Provider identification numbers
- South Dakota Medicaid State Plan
- Code of Federal Regulations

QUICK ANSWERS

1. **Does a child/adult need a referral from their Primary Care Provider/Health Home Provider for South Dakota Medicaid to cover a vaccine?**

   No, a referral is not needed for the administration of a vaccine.

2. **Can a recipient receive a vaccine at a pharmacy?**

   Yes, please refer to the Pharmacy Services manual for coverage, reimbursement, and claim instructions.

3. **Can a recipient acquire a physician administered drug through a pharmacy and take it to a physician or other licensed practitioner for administration?**

   No, physician administered drugs must not be billed to South Dakota Medicaid through the point of sale.

4. **If a recipient's primary health insurance requires a physician administered drug to be dispensed by a particular pharmacy, how should the drug be billed to South Dakota Medicaid?**

   South Dakota Medicaid does not cover physician administered drugs through the point of sale. The drug must be billed to South Dakota Medicaid on a CMS 1500 claim form.

5. **What reimbursement is available for vaccines acquired through the Vaccines for Children Program?**

   South Dakota Medicaid reimburses vaccines available through this program that are administered to recipients under age 19 at $0. The administration fee is reimbursed in accordance with the department's fee schedule.

6. **What vaccines are covered for individuals with limited Medicaid coverage?**

   All medically necessary vaccines that South Dakota Medicaid covers for full coverage recipients are covered for women in aid categories 77, 79 and 47. Medicaid will pay the co-payments and deductibles for recipients on aid category 73 if the vaccine is a Medicare part B covered service. Vaccines in the postpartum period for women in Aid category 79 are limited to vaccines administered during the inpatient stay.

7. **Are vaccines included in an FQHC/RHC encounter payment?**

   Vaccines/immunizations and administration are factored into each provider's PPS rate and are reimbursed as part of the PPS per diem when furnished incidental to a reimbursable medical PPS encounter. It is recommended that providers screen a recipient's immunization status and administer appropriate vaccines when seeing a recipient for their Well-Child or Well-Adult visit. For purposes of data collection, it is required that immunizations provided during a PPS encounter be included on the claim for PPS reimbursement.

   FQHCs/RHCs are allowed to bill for vaccines/immunizations and the associated administration provided on a date of service when a billable medical encounter did not occur. Standalone vaccines/immunizations may not be billed under the FQHCs/RHCs billing NPI. FQHC/RHCs billing for standalone vaccines/immunizations must utilize/acquire a separate billing NPI under a group enrollment with associated servicing NPIs and bill accordingly. The servicing provider must be enrolled with South Dakota Medicaid. Standalone vaccines/immunizations and the associated administration code will be reimbursed on a fee for service basis. Vaccines/immunizations may not be administered on a separate day than an FQHC/RHC encounter for the purpose of increasing the provider's reimbursement. For more information please refer to the FQHC/RHC Services manual.